

**APPLICATION UNDER UNITED STATES PATENT LAWS**

Invention: RECEPTOR BINDING ASSAYS FOR THE DETECTION OF TSH  
RECEPTOR AUTOANTIBODIES AND REAGENTS AND REAGENT KIT  
FOR CARRYING OUT SUCH A RECEPTOR BINDING ASSAY

Inventor(s): BERGMANN, Andreas  
STRUCK, Joachim  
MORGENTHALER, Nils  
WEGLOHNER, Wolfgang  
HOLLIDT, Jorg-Michael

Pillsbury Madison & Sutro LLP  
Intellectual Property Group  
1100 New York Avenue, N.W.  
Ninth Floor, East Tower  
Washington, D.C. 20005-3918  
Attorneys  
Telephone: (202) 861-3000

This is a:

- ☐ Provisional Application
- ☐ Regular Utility Application
- ☐ Continuing Application
- ☒ PCT National Phase Application
- ☐ Design Application
- ☐ Reissue Application
- ☐ Plant Application
- ☐ Substitute Specification  
Sub. Spec. filed \_\_\_\_\_  
in App. No. \_\_\_\_\_ / \_\_\_\_\_
- ☐ Marked Up Specification re  
Sub. Spec. filed \_\_\_\_\_  
in App. No. \_\_\_\_\_ / \_\_\_\_\_

**SPECIFICATION**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
REQUEST FOR FILING NATIONAL PHASE OF  
PCT APPLICATION UNDER 35 U.S.C. 371 AND 37 CFR 1.494 OR 1.495To: Asst. Commissioner of Patents  
Washington, D.C. 20231TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)Atty Dkt: PM 263260 | 2769US AS/KM  
M# | Client Ref.

From: Pillsbury Madison &amp; Sutro LLP, IP Group:

Date: September 15, 1999

This is a **REQUEST** for **FILING** a PCT/USA National Phase Application based on:

- | 1. International Application     | 2. International Filing Date      | 3. Earliest Priority Date Claimed  |
|----------------------------------|-----------------------------------|--|
| PCT/EP99/00159<br>↑ country code | 13 January 1999<br>Day MONTH Year | 15 January 1998<br>Day MONTH Year<br>(use item 2 if no earlier priority) |
4. Measured from the earliest priority date in item 3, this PCT/USA National Phase Application Request is being filed within:

(a) ☒ 20 months from above item 3 date (b) ☐ 30 months from above item 3 date,

(c) Therefore, the due date (unextendable) is 9/15/99

5. Title of Invention
- Receptor binding assays for the detection of TSH receptor autoantibodies and reagents and reagent kit for carrying out such a receptor binding assay

6. Inventor(s)
- BERGMANN, Andreas et al

Applicant herewith submits the following under 35 U.S.C. 371 to effect filing:

7. ☒ Please immediately start national examination procedures (35 U.S.C. 371 (f)).
8. ☐ A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is transmitted herewith (file if in English but, if in foreign language, file only if not transmitted to PTO by the International Bureau) including:
- a. ☐ Request;  
b. ☐ Abstract;  
c. \_\_\_\_\_ pgs. Spec. and Claims;  
d. \_\_\_\_\_ sheet(s) Drawing which are ☐ informal ☐ formal of size ☐ A4 ☐ 11"
9. ☒ A copy of the International Application has been transmitted by the International Bureau.
10. A translation of the International Application into English (35 U.S.C. 371(c)(2))
- a. ☒ is transmitted herewith including: (1) ☐ Request; (2) ☒ Abstract;  
(3) 42 pgs. Spec. and Claims;  
(4) 4 sheet(s) Drawing which are: ☐ informal ☒ formal of size ☒ A4 ☐ 11"
- b. ☐ is not required, as the application was filed in English.  
c. ☐ is not herewith, but will be filed when required by the forthcoming PTO Missing Requirements Notice per Rule 494(c) if box 4(a) is X'd or Rule 495(c) if box 4(b) is X'd.  
d. ☐ Translation statement attached (not required now).

11. ☒ **PLEASE AMEND** the specification before its first line by inserting as a separate paragraph:  
 a. ☒ --This application is the national phase of international application PCT /EP99 /00159  
 filed January 13, 1999 which designated the U.S.--  
 b. ☐ --This application also claims the benefit of U.S. Provisional Application No. 60/, filed
12. ☐ Amendments to the claims of the International Application **under PCT Article 19 (35 U.S.C. 371(c)(3))**, i.e., **before 18th month from first priority date above in item 3, are transmitted herewith (file only if in English) including:**
13. ☒ PCT Article 19 claim amendments (if any) have been transmitted by the International Bureau
14. ☐ Translation of the amendments to the claims **under PCT Article 19 (35 U.S.C. 371(c)(3))**, i.e., of **claim amendments** made before 18th month, **is attached (required by 20th month from the date in item 3 if box 4(a) above is X'd, or 30th month if box 4(b) is X'd, or else amendments will be considered canceled).**
15. **A declaration of the inventor (35 U.S.C. 371(c)(4))**  
 a. ☐ is submitted herewith ☐ Original ☐ Facsimile/Copy  
 b. ☒ is not herewith, but will be filed when required by the forthcoming PTO Missing Requirements Notice per Rule 494(c) if box 4(a) is X'd or Rule 495(c) if box 4(b) is X'd.
16. **An International Search Report (ISR):**  
 a. Was prepared by ☒ European Patent Office ☐ Japanese Patent Office ☐ Other  
 b. ☒ has been transmitted by the international Bureau to PTO.  
 c. ☒ copy herewith (2 pg(s).) ☒ plus Annex of family members (1 pg(s).)
17. **International Preliminary Examination Report (IPER):**  
 a. ☒ has been transmitted (if this letter is filed after 28 months from date in item 3) in English by the International Bureau with Annexes (if any) in original language.  
 b. ☐ copy herewith in English.  
 c.1 ☐ IPER Annex(es) in original language ("Annexes" are amendments made to claims/spec/drawings during Examination) including attached amended:  
 c.2 ☐ Specification/claim pages #  claims #   
 Dwg Sheets #   
 d. ☐ Translation of Annex(es) to IPER **(required by 30<sup>th</sup> month due date, or else annexed amendments will be considered canceled).**
18. **Information Disclosure Statement** including:  
 a. ☒ Attached Form PTO-1449 listing documents  
 b. ☒ Attached copies of documents listed on Form PTO-1449  
 c. ☒ A concise explanation of relevance of ISR references is given in the ISR.
19. ☐ **Assignment** document and Cover Sheet for recording are attached. Please mail the recorded assignment document back to the person whose signature, name and address appear at the end of this letter.
20. ☐ Copy of Power to IA agent.
21. ☐ **Drawings** (complete only if 8d or 10a(4) not completed):  sheet(s) per set: ☐ 1 set informal;  
☐ 1 set formal of size ☐ A4 ☐ 11"
22. ☐  (No.) **Verified Statement(s)** establishing "small entity" status under Rules 9 & 27
23. **Priority** is hereby claimed under 35 U.S.C. 119/365 based on the priority claim and the certified copy, both filed in the International Application during the international stage based on the filing in (country) GERMANY of:
- |     | <u>Application No.</u> | <u>Filing Date</u>      |     | <u>Application No.</u> | <u>Filing Date</u> |
|-----|------------------------|-------------------------|-----|------------------------|--------------------|
| (1) | <u>198 01 319.1</u>    | <u>January 15, 1998</u> | (2) | <u></u>                | <u></u>            |
| (3) | <u></u>                | <u></u>                 | (4) | <u></u>                | <u></u>            |
| (5) | <u></u>                | <u></u>                 | (6) | <u></u>                | <u></u>            |
- a. ☒ See Form PCT/IB/304 sent to US/DO with copy of priority documents. If copy has not been received, **please proceed promptly to obtain same from the IB.**
- b. ☐ Copy of Form PCT/IB/304 attached.

514 Rec'd T/PTO 15 SEP 1999

24. Attached:

## 25. Preliminary Amendment:

25.5 Per Item 17.c3, **cancel original** pages # \_\_\_\_\_, claims # \_\_\_\_\_, Drawing Sheets # \_\_\_\_\_26. **Calculation of the U.S. National Fee (35 U.S.C. 371 (c)(1)) and other fees is as follows:**  
based on amended claim(s) per above item(s) ☐ 12, ☐ 14, ☐ 17, ☐ 25, ☐ 25.5 (hiliate)

					Fee Code (lg/sm entity) (see box 22)	
Total Effective Claims	minus 20 =	0	x \$18/\$9	=	\$0	966/967
Independent Claims	minus 3 =	0	x \$78/\$39	=	\$0	964/965
If any proper (ignore improper) Multiple Dependent claim is present,			add \$260/\$130		+0	968/969

BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(4)): →→BASIC FEE REQUIRED, NOW→→→

A. If country code letters in item 1 are not "US", "BR", "BB", "TT", "MX", "IL", "NZ", or "IN"

See item 16 re:

1. Search Report was <u>not</u> prepared by EPO or JPO	-----	add \$970/\$485		960/961
2. Search Report was prepared by EPO or JPO	-----	add \$840/\$420	+840	970/971

SKIP B, C, D AND E UNLESS country code letters in item 1 are "US", "BR", "BB", "TT", "MX", "IL", "NZ", or "IN"

→ <input type="checkbox"/> B. If <u>USPTO</u> did not issue <u>both</u> International Search Report (ISR) <u>and</u> (if box 4(b) above is X'd) the International Examination Report (IPER),	-----	add \$970/\$485	+	960/961
(only) → <input type="checkbox"/> C. If <u>USPTO</u> issued ISR but not IPER (or box 4(a) above is (one) X'd),	-----	add \$760/\$380	+	958/959
(of) → <input type="checkbox"/> D. If <u>USPTO</u> issued IPER but IPER Sec. V boxes <u>not all</u> 3 (these) YES,	-----	add \$670/\$335	+	956/957
( 4) → <input type="checkbox"/> E. If international preliminary examination fee was paid to (boxes) <u>USPTO</u> and Rules 492(a)(4) and 496(b) <u>satisfied</u> (IPER Sec. V <u>all</u> 3 boxes YES for <u>all</u> claims),	-----	add \$96/\$48	+	962/963

27. SUBTOTAL = \$840

28. If Assignment box 19 above is X'd, add Assignment Recording fee of ----\$40 +0 581

29. Attached is a check to cover the ----- TOTAL FEES \$840

Our Deposit Account No. 03-3975

Our Order No. 11377 263260

C#

M#

**CHARGE STATEMENT:** The Commissioner is hereby authorized to charge any fee specifically authorized hereafter, or any missing or insufficient fee(s) filed, or asserted to be filed, or which should have been filed herewith or concerning any paper filed hereafter, and which may be required under Rules 16-18 and 492 (missing or insufficient fee only) now or hereafter relative to this application and the resulting Official document under Rule 20, or credit any overpayment, to our Account/Order Nos. shown above for which purpose a duplicate copy of this sheet is attached.

This CHARGE STATEMENT does not authorize charge of the issue fee until/unless an issue fee transmittal form is filedPillsbury Madison & Sutro LLP  
Intellectual Property Group1100 New York Avenue, N.W.  
Ninth Floor East Tower  
Washington, D.C. 20005-3918  
Tel: (202) 861-3000  
Atty/Sec: PNK/mhn

By: Atty: Paul N. Kokulis

Sig:

Reg. No. 16773

Fax: (202) 822-0944  
Tel: (202) 861-3503NOTE: File in duplicate with 2 postcard receipts (PAT-103) & attachments.